

Docket No.: SER-001
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Letters Patent of:
Seymour Fein

Patent No.: 7,799,761

Issued: September 21, 2010

For: Pharmaceutical Compositions Including Low
Dosages of Desmopressin

Mail Stop: Petitions
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

PETITION UNDER 37 C.F.R. § 1.181 FOR RECONSIDERATION OF
PATENT TERM ADJUSTMENT

Dear Sir:

Petitioner requests that the decision made in the Decision on Patent Term Adjustment (PTA) mailed by the Office on August 17, 2010, be reviewed and reconsidered. Petitioner submits that the petition to the Director is appropriate because, as outlined below, applicants requested reconsideration of the Office's determination of PTA and this is not an appealable issue. Also, this petition is filed within two months of the Office's final action with respect to one of the grounds on which petitioner requested reconsideration of PTA. This petition is accompanied by the petition fee set forth in § 1.17(f). The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith to our Deposit Account No. 07-1700, under Order No. SER-001.

The following relevant statement of facts apply. The facts are supported by the official PTO record. Applicant filed an "Application for Patent Term Adjustment" on May 20, 2010, in which additional PTA was requested on three grounds. First, applicant requested recalculation under 37 C.F.R. § 1.702(b) for the failure of the Office to issue the patent within three years. The Office dismissed this request as premature. Second, an additional 30 days of patent term under § 1.702(a)(2) was requested in connection with a non-final Office action issued on October 16, 2007, more than 4 months after applicant's May 16, 2007, reply. The Office dismissed this request. Third, applicant requested that the Office reconsider an 87 day period of delay attributed to applicant under 37 C.F.R. 1.704(c)(8) for the filing of an Information Disclosure Statement after an appeal brief was filed. Petitioner thanks the Office for granting this request and removing the 87 day period of delay.

Petitioner respectfully requests reconsideration of the second ground for recalculation, namely, that the Office failed to issue an action within four months of applicant's previous reply as required in 37 C.F.R. § 1.702(a)(2). As asserted in the Application for Patent Term Adjustment submitted May 20, 2010, applicant submitted a reply to final Office action, together with an RCE, on May 16, 2007. Although a non-final Rejection was mailed August 6, 2007, it was subsequently withdrawn on October 16, 2007, and a new non-final rejection was issued because "the Examiner recognized that the previous issued non-final Office action required further clarification..." (see Office action dated October 16, 2007, page 2, second paragraph). Applicant submits that the withdrawal of a timely Office action and issuance of a new Office action after four months from the date a reply was filed should not be considered timely for the purposes of patent term adjustment. Enactment of 35 U.S.C. § 154 was, in part, to "guarantee...prompt Patent and Trademark Office response" (see, *e.g.*, § 154(b)(A)). Permitting the Office to issue an action within the time limit, only to withdraw the action and replace it with a new action after the expiry of the four month time limit, not only delays prosecution but requires the applicant to restart consideration of the initial Office action in view of the new Office action. The same rationale is used to justify reducing patent term for an applicant who files a supplementary paper after an initial reply, and therefore should also apply to the Office (see *Changes to Implement Patent Term Adjustment Under Twenty Year Patent Term*, 65 Fed. Reg. 56,372, Col. 3, first paragraph ("The submission of a supplemental reply

or other paper (e.g., an information disclosure statement (IDS) or petition) after an initial reply was filed requires the Office to restart consideration of the initial reply in view of the supplemental reply or other paper, which will result in a delay in the Office's response to the initial reply.'').

Furthermore, based on a discussion with a member of the Office of Patent Legal Administration, the undersigned understands that when an Office action is withdrawn by a Letter Withdrawing/Vacating Office Action, signed by a Technology Center Director, the withdrawn Office action is not considered to have issued for purposes of patent term adjustment calculation. In the present application, the Office has acted with identical effect in withdrawing the Office action of August 6, 2007, as requiring further clarification and replacing it with the Office action of October 16, 2007. As such, only the Office action of October 16, 2007 would properly be considered in the calculation of patent term adjustment.

Accordingly, petitioner respectfully submits that the refusal to add 30 days of PTA is not consistent with USPTO term adjustment practice. Therefore, petitioner requests that the patent term adjustment calculation be corrected to include a 30 day extension based on the Office's delay.

If for any reason, this Petition is found not to comply with the requirements of 37 C.F.R. § 1.181 or is otherwise found improper, please call the undersigned agent.

Respectfully submitted,

Date: October 17, 2010

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